

K062559

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5. 510(k) Summary

Premarket Notification Summary

JAN 29 2007

1. Sponsor Information:
Laboratories URGO
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21300 Chenove
France

Contact Person: Sophie Fortin
Regulatory Affairs Manager
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2. Device Name:
Common or Usual Name: Antimicrobial Wound Dressing with Silver
Proprietary Name: Urgocell® Ag
Classification Name: Unclassified

3. Predicate Devices:
Contreet-Foam Antibacterial wound Dressing (K022416), Coloplast Corp.
Urgotul® Ag Antimicrobial wound dressing with silver (K061220), Laboratoires URGO

4. Description of Device
Urgocell® Ag wound dressing is a sterile, antimicrobial absorbent wound contact dressing with silver.

Urgocell® Ag wound dressing is non-occlusive and non-adhesive for painless removal.

Urgocell® Ag is composed of three layers :

- in contact with the wound, a polyester mesh impregnated with a matrix of carboxymethylcellulose hydrocolloid particles, cohesion polymers and Vaseline containing silver,
- a non-sensitising, super-absorbent polyurethane foam pad,
- a protective, semi-permeable polyurethane backing.

5. Indications for Use

The barrier functions of Urgocell® Ag, antimicrobial wound dressing, may help reduce infection in moderately to high exuding partial and full thickness wounds including decubitus ulcers, venous stasis ulcers , diabetic ulcers , first and second degree burns, donor and graft sites.

6. Description of Safety and Substantial Equivalence:

Safety Studies

A standard battery of safety and biocompatibility studies have been conducted including:

- Cytotoxicity

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- Irritation study in rabbit
- Sensitization study in guinea pigs

The results of the biocompatibility studies are considered to be comparable to predicate devices and other silver containing wound dressings.

Studies of the antimicrobial activity of Urgocell® Ag wound dressing have been conducted against *MRSA*, *Pseudomonas aeruginosa*, and *Streptococcus pyogenes*. Results demonstrated that the antibacterial activities are comparable to those of the predicate devices.

Substantial Equivalence

Urgocell® Ag wound dressing compared to Contreet F and Urgotul® Ag : all three contain silver as the active antimicrobial agent. All three provide comparable functions and indications for use. Urgocell® Ag wound dressing, Contreet® Foam and Urgotul® Ag are substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Laboratories URGO
% Ms. Sophie Fortin
Manager, Regulatory Affairs
42 Rue de Longvic
21300 Chenove
France

JAN 29 2007

Re: K062559

Trade/Device Name: Urgocell AG Antimicrobial Wound Dressing with Silver
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 10, 2006
Received: November 16, 2006

Dear Ms. Fortin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

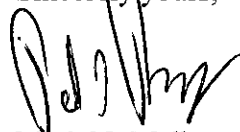
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 062559

Indications for Use

510(k) Number (if known): K 062559

Device Name: Urgocell® Ag

Indications For Use:

The barrier functions of Urgocell® Ag, antimicrobial wound dressing, may help reduce infection in moderately to high exuding partial and full thickness wounds including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, donor and graft sites.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K 062559